Connecticut General Assembly

February 23, 2012

TO: Chairs and Ranking Members of the Appropriations, Human Services, Insurance and Real Estate, and Public Health Committees

FROM: Senator Toni Harp, Task Force Co-chair
Representative Peter Tercyak, Task Force Co-chair

RE: Childhood Immunization Task Force Report

In accordance with Public Act 11-44, § 163, we hereby submit to the Appropriations, Human Services, Insurance and Real Estate, and Public Health Committees the report and recommendations of the Childhood Immunization Task Force. The task force hopes the committees will consider these recommendations during their deliberations in the 2012 session.

We would be happy to meet with you and the committees at your convenience regarding this report.

cc: Nicholas C. Varunes, Clerk of the House of the Representatives
Garey E. Coleman, Clerk of the Senate
Appropriations Committee
Human Services Committee
Insurance and Real Estate Committee
Public Health Committee
Office of Legislative Research
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Connecticut General Assembly

Report of the Childhood Immunization Task Force under PA 11-44

February 23, 2012

TASK FORCE MEMBERS

Public Act 11-44 (§ 163), An Act Concerning the Bureau of Rehabilitative Services and Implementation of Provisions of the Budget Concerning Human Services and Public Health, established a task force to (1) consider whether the state should continue universal childhood immunizations and (2) develop a plan concerning specified aspects of the state's childhood immunization program.

The task force members are:

Senator Toni Harp, Task Force Co-chair
Representative Peter Tercyak, Task Force Co-chair
Robert Baltimore, M.D., American Academy of Pediatrics of CT
Janet Brancifort, Department of Public Health
Representative Chris Coutu, Member of the General Assembly
Senator Joseph Crisco, Member of the General Assembly
Sara Johnson Davis, Novartis Pharmaceuticals
Anne Foley, Office of Policy and Management
Senator Terry Gerratana, Member of the General Assembly
Representative Lile Gibbons, Member of the General Assembly
Senator Robert Kane, Member of the General Assembly
Senator Kevin Kelly, Member of the General Assembly
Nicholas Korns, M.D., Connecticut Association of Health Plans
Senator Joe Markley, Member of the General Assembly
Representative Robert Megna, Member of the General Assembly
Representative Craig Miner, Member of the General Assembly
Senator Anthony Musto, Member of the General Assembly
Representative Jason Perillo, Member of the General Assembly
Representative Betsy Ritter, Member of the General Assembly
Vincent Sacco, Department of Public Health
Charles Thompson, M.D., Pfizer Pharmaceutical Company
Stephen Updegrove, M.D., American Academy of Pediatrics of CT
Representative Toni Walker, Member of the General Assembly
Senator Jason Welch, Member of the General Assembly
Robert Zavoski, M.D., Department of Social Services
Peter Zelez, Department of Insurance

TASK FORCE CHARGE

Section 163 of Public Act 11-44 required the task force to consider whether the state should continue universal childhood immunizations. The act also required the task force to develop a plan to:

1. maintain access to high-quality immunizations for children in the state;

2. determine how to respond to recommendations by the federal Centers for Disease Control and Prevention (CDC) for new childhood immunizations not currently provided by the Department of Public Health's (DPH) immunization program;

3. permit health care providers who administer vaccines to children under the federal Vaccines for Children program to select, and DPH to provide, vaccines licensed by the federal Food and Drug Administration; and

4. determine how best to cover the cost of immunizations for children in the state.

The task force was required to report its findings and recommendations, including recommendations for legislation, to the Appropriations, Human Services, Insurance and Real Estate, and Public Health committees by February 1, 2012.

TASK FORCE MEETINGS AND PRESENTATIONS

The task force met eight times (see Appendix A for a list of meeting dates) and heard presentations from the following:

1. Dr. Robert Baltimore, American Academy of Pediatrics of CT;

2. Janet Brancifort, public health service manager, Family Health Section and Vincent Sacco, program manager, Immunization Program, Department of Public Health;

3. Sara Johnson Davis, Novartis Pharmaceuticals;

4. Nicole Dube and James Orlando, Office of Legislative Research;

5. Dr. Stephen Updegrove, American Academy of Pediatrics of CT; and

6. Peter Zelez, fiscal administrative manager, Department of Insurance.

The following people and organizations presented or submitted proposed recommendations:

1. Sara Johnson Davis, Novartis Pharmaceuticals;

2. Anne Foley, Office of Policy and Management;

3. GlaxoSmithKline;

4. Insurance Association of Connecticut;

5. Dr. Nicholas Korns, Connecticut Association of Health Plans;

6. New England Biotechnology Association and CT United for Research Excellence, Inc.;

7. Vincent Sacco, Department of Public Health;

8. Dr. Charles Thompson, Pfizer Pharmaceutical Company;

9. Dr. Stephen Updegrove, American Academy of Pediatrics of CT;

10. Dr. Robert Zavoski, Department of Social Services; and

11. Peter Zelez, Department of Insurance.

A list of the reports, submissions, and other material the task force received can be found in Appendix B at the end of this report.

BACKGROUND: CONNECTICUT'S CHILDHOOD IMMUNIZATION PROGRAM

The Department of Public Health (DPH) operates a federal "Vaccines for Children" (VFC) entitlement program and its own state immunization program funded by an insurance assessment. To fund the state program, each domestic insurer or HMO conducting life or health insurance business in the state must pay an annual "health and welfare" fee to the Insurance Department. The fees are calculated based on life and health insurance premiums and subscriber charges in the same manner as the state's Insurance Fund (CGS § 38a-48). The funds the Insurance Department collects are deposited into the General Fund. This allows DPH to purchase the vaccines at no cost to the state, which it does, at a discount, through federal government contracts.

VFC Immunization Program

The VFC program provides all 16 routine childhood vaccinations recommended by the CDC's Advisory Committee on Immunization Practices (ACIP) free of charge to children who are Medicaid-eligible, uninsured, underinsured, Native Alaskan, or American Indian (see Table 1). The state's Medicaid plan must include coverage for the administration of the vaccines.

Table 1: Vaccines Required Under the VFC Program

ACIP Recommended Vaccines	
Diphtheria	Mumps
	Pertussis (whooping cough)
Hepatitis A	Pneumococcal disease (pneumonia)
Hepatitis B	Polio
Human Papillomavirus (HPV)	Rotavirus
Influenza (flu)	Rubella (German measles)
Measles	Tetanus (lockjaw)
Meningococcal disease (meningitis)	Varicella (chickenpox)

A child is considered underinsured if he or she has private health insurance but that coverage (1) does not include vaccines, (2) includes only certain vaccines, or (3) is limited to a certain amount. Underinsured children are only eligible for VFC vaccines not covered by their private health insurance and can only receive them through a rural health clinic or federally qualified health center.

Participating healthcare providers can charge administrative and office visit fees for administering the vaccine. However, they are required by law to waive the administrative fee if the child's family cannot afford to pay it. The state's Medicaid program pays providers to administer the vaccines to Medicaid-eligible children.

Universal Select Program

By law, DPH must also administer a state childhood vaccination program that provides certain vaccines, including combination vaccines, at no cost to healthcare providers within available appropriations. Vaccines must be made available to all children who are ineligible for the VFC program regardless of insurance status. Connecticut's program is a "universal-select" vaccine purchase program, meaning that it provides most (11) but not all of the 16 ACIP-recommended vaccines to children through age 18. Vaccines not supplied by the program are pneumococcal, rotavirus, influenza, hepatitis A, and HPV. Physicians must purchase these five vaccines privately and bill the child's insurance carrier for the cost and administration of the vaccine.

According to DPH, in FY 11 the state program cost $8,829,534. The department estimates that it would cost approximately an additional $24,462,012 to expand to a "universal" vaccine program that provides all 16 CDC-recommended vaccines (see Table 2).

Table 2: Estimated State Cost of Expanding to a Universal Vaccine Purchase Program

Vaccine	*Age*	*Number of Doses*	*Number of Children*	*Cost Per Dose*	*Total Cost*
Pneumococcal conjugate (PCV)[1]	2-15 months	4	22,796	$97.21	$8,863,997
Hepatitis A[2]	1 year	2	24,213	$14.25	$690,071
Rotavirus[3]	2-8 months	2	22,796	$89.25	$4,069,086
HPV[4]	11 years	3	30,155	$95.75	$8,662,024
Influenza[5]	6-35 months	2/1*	59,823	~$12.00	$1,292,172
	3-4 years	2/1**	49,770	~$11.85	$884,662
TOTAL COST					**$24,462,012**

Source: DPH presentation, December 1, 2011 (Data based on National Center for Immunization and Respiratory Diseases, Connecticut population estimate for 2012).

1. PCV estimate based on children less than 1 year of age (22,796 children).
2. Hepatitis A estimate based on children 1-2 years of age (24,213 children).
3. Rotavirus estimate based on children less than 1 year of age (22,796).
4. HPV estimate based on one cohort of 11 year olds (children 7-18 years of age = 361,858/12 = 30,155).
5. Influenza estimate:
   *6-35 month age group – total number of children in this age group is 59,823. DPH estimates that only 80% of this total population will need two doses of flu vaccine and remaining 20% will need one dose.
   **3-4 year age group – total number of children in this age group is 49,770. DPH estimates that 50% of 3-4 year olds will need two doses of flu vaccine and 50% will need one dose.

Provider Brand Choice

The VFC program pays for any brand of vaccine recommended by the ACIP. But DPH chooses the brand for each vaccine provided by both the VFC and state programs; providers have no choice. The department makes its decisions based on the recommendations of its Vaccine Purchase Advisory Committee (VPAC), which considers the following criteria:

1. vaccine cost for a "full series" of shots,

2. ease of use (e.g., vaccines with the least number of required injections or provider visits), and

3. safety and efficacy recommendations by the CDC and other national advisory bodies.

DPH chooses a single vaccine when more than one manufacturer offers a product with similar efficacy, safety, and cost. If two vaccines have the same efficacy and safety, the department will provide the less expensive vaccine so that it can immunize more children. It does not switch vaccine manufacturers without a significant reason in order to maintain product consistency and prevent the mixing and matching of vaccines.

The department is conducting a (1) feasibility study on transitioning to a "full-choice" VFC program and (2) vaccine choice pilot program with one VFC provider in Hartford, Charter Oak Health Center, Inc., that began on November 1, 2011. The department must report to the Public Health Committee by June 1, 2012 on the pilot's results and any recommendations for future program expansion. If the pilot program does not show (1) a significant reduction in child immunization rates or (2) an increased risk to children's health and safety, it will expand to all VFC providers starting July 1, 2012.

Table 3 lists the U.S. vaccine brands for the 16 vaccines that are part of the VFC program.

Table 3: U.S. Vaccine Brands for VFC Vaccines (Including Combination Vaccines)

Vaccine	*Brand*	*Manufacturer*
DT (Diphtheria and tetanus)	(Generic)	Sanofi
DTaP (Diphtheria, tetanus, and pertussis)	Daptacel	Sanofi
	Infanrix	GlaxoSmithKline
DTaP/ Hep B/ IPV (Polio)	Pediarix	GlaxoSmithKline
DTaP/ IPV	Kinrix	GlaxoSmithKline
DTaP/ IPV/ Hib	Pentacel	Sanofi
Haemophilus Influenzae Type B (Hib)	ActHIB	Sanofi
	Hiberix	GlaxoSmithKline
	PedvaxHIB	Merck
Hib/ Hep B	Comvax	Merck
Hepatitis A	Havrix	GlaxoSmithKline
	Vaqta	Merck
Hepatitis B	Engerix-B	GlaxoSmithKline
	Recombivax HB	Merck
Hep A/ Hep B	Twinrix	GlaxoSmithKline
HPV	Cervarix	GlaxoSmithKline
	Gardasil	Merck
Influenza	Afluria	CSL
	Agriflu	Novartis
	Fluarix	GlaxoSmithKline
	FluLaval	GlaxoSmithKline
	FluMist	Medimmune
	Fluvirin	Chiron
	Fluzone	Sanofi
MMR (Measles, Mumps, and Rubella)	M-M-R II	Merck
MMRV (MMR and varicella)	ProQuad	Merck
Meningococcal	Menactra	Sanofi
	Menomune	Sanofi
	Menveo	Novartis
Pneumococcal	Pneumovax 23	Merck
	Prevnar 13	Wyeth
Polio	Ipol	Sanofi
Rotavirus	Rota Teq	Merck
	Rotarix	GlaxoSmithKline
Td (Tetanus and reduced Diphtheria)	Decavac	Sanofi
	(Generic)	Massachusetts Biological Labs
Tdap (Tetanus, reduced Diphtheria, and reduced Pertussis)	Adacel	Sanofi
	Boostrix	GlaxoSmithKline
Tetanus toxoid	(Generic)	Sanofi
Varicella	Varivax	Merck

Source: CDC, Epidemiology and Prevention of Vaccine-Preventable Diseases, The Pink Book: Course Textbook, 12th Edition (April 2011), Appendix B, *available at* http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf.

RECOMMENDATIONS FOR LEGISLATIVE ACTION

The following recommendations reflect a majority vote of task force members. Members acknowledge that given the complexity of the issue and the short time frame for completing its work, further discussion is needed in order to reach a consensus.

The task force supports the goal of universal vaccine compliance, due to the well-established public health benefits of childhood vaccinations. To further this goal, the task force recommends that:

1. while it would be best to give providers full choice over the vaccines to select for their patients, funding constraints must be considered; therefore, by July 1, 2012 providers should be able to choose a vaccine brand other than one recommended by VPAC as long as doing so would be cost-neutral;

2. VPAC should continue to recommend vaccine products, based on cost as well as other factors to optimize Connecticut's goal of fully immunizing its children in a timely fashion; DPH should inform providers of VPAC's recommendations and the rationales behind them;

3. the state incrementally increase the amount of the General Fund appropriation for the purchase, storage, and distribution of vaccines under the program, as budgetary resources allow;

4. the state broaden the insurance assessment pool so that it is equitable, and in doing so, a successor body evaluate (a) who to include in the pool (for example, include self-insurers or exclude life insurers) and (b) other state insurance assessment models; and

5. given the complexity of the issues the task force addressed, as well as the importance of achieving the highest possible rate of childhood immunization in a cost-effective manner, a successor task force or similar body should continue to evaluate and monitor the following issues in greater depth:

    - the findings of the vaccine choice pilot program, created by PA 11-242;

    - a comprehensive analysis of the logistics, implementation, and impact of a cost-neutral choice system in the non-VFC population; and

- the conditions and implications of requiring mandatory provider participation in the state childhood immunization program.

MINORITY REPORT

Task Force members Sen. Joseph Markley, Sen. Kevin Kelly, Sen. Robert Kane, and Sen. Jason Welch submitted the following minority report with two recommendations:

1. Maintain the current state funded vaccination program until 2014.

Should the Patient Protection and Affordable Care Act (PPACA) remain intact in 2014 and should adequate federal funding be dedicated towards the federal vaccines for children program, Connecticut's state funded program will no longer be necessary. With the new requirement that insurers provide coverage for vaccines without copays or out of pocket costs, the population that was formerly covered by the state's immunization program will be covered by private insurance.

Four years before the federal VFC program came into existence, Connecticut passed legislation in 1991 that required the state to "provide vaccine at no cost to health care providers in Connecticut to administer to children so that cost of vaccine will not be a barrier to age-appropriate vaccination in this state." Since then, the cost of vaccines have been paid for by three main groups: (1) the federal government (VFC program), (2) state government, through an assessment on insurers (CT vaccination program), and (3) individuals via private insurance.

Connecticut's immunization program and the federal program have been designed primarily to provide vaccines to low-income individuals and to those without adequate insurance so that the cost of vaccinations does not become prohibitive. With the passage of the PPACA, insurers will be required to cover vaccinations (with no copays) as recommended by the CDC's Advisory Committee on Immunization Practices.

Should Connecticut eliminate its state financed vaccination program, children who currently receive vaccinations will continue to receive appropriate and recommended vaccinations. Since Connecticut's immunization program is designed for individuals without insurance or inadequate insurance and the PPACA will cover this group, there should be no gap in coverage.

While there may be concerns that a shift in coverage will result in a decreased childhood vaccination rate, experience in other states (specifically those with only a VFC program) show that states with a dual vaccination program (state and federal) do not necessarily have higher vaccination rates then those states with only a VFC program. For example, Connecticut's vaccination rate is 76% (the U.S. average is 75%). However, Florida – which only has a VFC program – has a vaccination rate of 86%.

Additionally, we believe – as do many members of the task force – that increased provider choice (if cost-neutral) can be of great benefit. Elimination of the state funded immunization program would help to expand provider choice with regard to vaccinations in the non-VFC program. While there may be additional costs in transitioning the state immunization program to a "full-choice" program, eliminating the program and utilizing private insurance would open up provider choice at no cost.

Currently, the state picks the vaccine that providers will use in the state immunization program. However, under the PPACA, there does not appear to be any guidelines in place at this time that would allow insurers to restrict the type of vaccines that providers administer. Thus, the population that was formerly served by the state program would now be free to have a provider that has choice over the vaccine that they will use. Additionally, DPH is currently exploring the option of converting the VFC program into a "full choice" program.

Lastly, should Connecticut eliminate its state funded vaccination program, it will be essential that Connecticut's congressional delegation work to ensure that adequate funding remains in place.

2. The immunization program should remain in the general fund and the cost should no longer be borne by one industry.

Prior to 2003, the childhood immunization program was funded from general tax revenues. In an attempt to close a budget shortfall, the cost of the program was shifted to an assessment on both health and life insurers. This shift created fundamental unfairness in two ways. First, as vaccines are recognized as a broad based benefit to society, it would follow that cost would be borne by society. We do not require that parents of schoolchildren pay proportionately more for education or that those municipalities with highways running through pay more for their maintenance.

Second, of the two main groups that are assessed, life insurers have no real nexus to the product that they are being assessed for. While the task force tacitly addresses this issue in recommendation #4 that states that the state should "broaden the insurance assessment pool so that it is equitable," the question about whether or not insurers should be assessed is unanswered.

Furthermore, the assessment against insurers should more appropriately be called a tax on health and life insurance policies. Removing the childhood immunization program from the general fund would all but guarantee that insurer assessments would increase and ultimately costs for consumers would increase. The whole rationale for keeping items in budget is so that their costs can be fairly assessed by the legislature. Removing the childhood immunization program from the general fund would remove this transparency and accountability.

Task Force Report Prepared By:
Nicole Dube & James Orlando
Office of Legislative Research
Connecticut General Assembly
Report # 2012-R-0117

APPENDIX A

Task Force Meeting Dates

November 17, 2011
December 1, 2011
December 15, 2011
January 5, 2012
January 12, 2012
January 19, 2012
February 2, 2012
February 16, 2012

APPENDIX B
SUBMISSIONS, REPORTS, AND BACKGROUND MATERIAL[1]

1. Public Act 11-44, *An Act Concerning the Bureau of Rehabilitative Services and Implementation of Provisions of the Budget Concerning Human Services and Public Health*;

2. Department of Public Health, *Childhood Immunization Task Force: Selection of Vaccines*, presented December 1, 2011;

3. Centers for Disease Control and Prevention, *Vaccination Coverage of U.S. Adolescents 13-17 Years, National Immunization Survey-Teen, 2006*, (presented by DPH on December 1, 2011);

4. Peter Zelez, Department of Insurance, *Funding Childhood Immunizations in Connecticut*, presented December 1, 2011;

5. Robert Baltimore, M.D., Yale University School of Medicine, *Childhood Vaccines*, presented December 15, 2011;

6. Statement of Clement Lewin, Head of Medical Affairs and Immunization Strategy, Novartis Vaccines, presented by Sara Johnson Davis, Novartis Pharmaceuticals, on December 15, 2011;

7. Dr. Stephen Updegrove, American Academy of Pediatrics of CT, *A Pediatric Perspective from the CT Chapter of the AAP*, presented December 15, 2011;

8. Nicole Dube and James Orlando, Office of Legislative Research, *Childhood Immunization: Other States*, presented December 15, 2011 (part 1) and January 12, 2012 (part 2);

9. Department of Public Health Immunization Program, *Vaccine Choice Feasibility Study* (Booz Allen Hamilton, revised November 25, 2011), presented February 2, 2012;

10. Sara Johnson Davis, Novartis Pharmaceuticals, Proposed Recommendations;

11. Anne Foley, Office of Policy and Management, Proposed Recommendations;

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[1] Copies of the following materials are on file with the Public Health committee.

12. GlaxoSmithKline, Proposed Recommendations;

13. Insurance Association of Connecticut, Proposed Recommendations;

14. Dr. Nicholas Korns, Connecticut Association of Health Plans, Proposed Recommendations;

15. New England Biotechnology Association and CT United for Research Excellence, Inc., Proposed Recommendations;

16. Vincent Sacco, Department of Public Health, Proposed Recommendations;

17. Dr. Charles Thompson, Pfizer Pharmaceutical Company, Proposed Recommendations;

18. Dr. Stephen Updegrove, American Academy of Pediatrics of CT, Proposed Recommendations;

19. Dr. Robert Zavoski, Department of Social Services, Proposed Recommendations;

20. Peter Zelez, Department of Insurance, Proposed Recommendations;

21. Insurance Department's Statement Regarding Its Abstention from Voting on Final Recommendations; and

22. Vaccine Purchase Advisory Committee Membership List.